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NOTICE OF ALLOWANCE AND FEE(S) DUE

7590

Nixon Peabody Clinton Square P.O. Box 31051

12/04/2009

EXAMINER

HA, JULIE PAPER NUMBER ARTHNIT

1654

Rochester, NY 14603-1051 DATE MAILED: 12/04/2009

APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO 10/552.110 07/03/2006 Robert Peter Millar 20747/300 4173

TITLE OF INVENTION; GONADOTROPIN RELEASING HORMONE ANALOGUES CONJUGATES WITH STEROID HORMONES

| APPLN, TYPE | SMALL ENTITY | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(S) DUE | DATE DUE |
|----------------|--------------|---------------|---------------------|----------------------|------------------|------------|
| nonprovisional | NO | \$1510 | \$300 | \$0 | \$1810 | 03/04/2010 |

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. <u>PROSECUTION ON THE MERITS IS CLOSED.</u> THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

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B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where

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| Nixon Peabody Clinton Square P.O. Box 31051 | <i>y</i> | 2209 | I S a u | Ce hereby certify that that tates Postal Service ddressed to the Mai ansmitted to the USI | rtificate nis Fee(with sur I Stop TO (57 | e of Mailing or Trans: (s) Transmittal is being fficient postage for firs ISSUE FEE address 71) 273-2885, on the d | mission g deposited with the United st class mail in an envelope above, or being facsimile ate indicated below. |
| Rochester, NY 1 | 14603-1051 | | | | | | (Depositor's name) |
| | | | | | | | (Signature) |
| | | | L | | | | (Date) |
| APPLICATION NO. | FILING DATE | | FIRST NAMED INVENT | OR | ATTC | ORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/552,110 TITLE OF INVENTION | 07/03/2006 I: GONADOTROPIN RE | ELEASING HORMONE | Robert Peter Millar ANALOGUES CONJU | GATES WITH STEI | ROID H | 20747/300 IORMONES | 4173 |
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| nonprovisional | NO | \$1510 | \$300 | \$0 | | \$1810 | 03/04/2010 |
| EXAM | IINER | ART UNIT | CLASS-SUBCLASS | 7 | | | |
| HA, J | | 1654 | 514-015000 | _ | | | |
| "Fee Address" ind PTO/SB/47; Rev 03-0 Number is required. 3. ASSIGNEE NAME A | ondence address (or Cha B/122) attached. ication (or "Fee Address)2 or more recent) attach ND RESIDENCE DATA | "Indication form ed. Use of a Customer | (I) the names of up or agents OR, altern (2) the name of a si registered attorney 2 registered patent a listed, no name will THE PATENT (print or | ngle firm (having as or agent) and the nan ttorneys or agents. If be printed. type) | a memb nes of u no nan | per a 2pto | |
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| 4a. The following fee(s) Issue Fee Publication Fee (N | vo small entity discount p | | b. Payment of Fee(s): (F A check is enclose Payment by credit The Director is her overpayment, to De | d. card. Form PTO-203 | B is atta | ached. required fee(s), any de | |
| | s SMALL ENTITY state | as. See 37 CFR I.27. | | | | TITY status. Sec 37 Cl | |
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| This collection of inform an application. Confiden submitting the complete this form and/or suggesti Box 1450, Alexandria, V Alexandria, Virginia 223 | nation is required by 37 C tiality is governed by 35 d application form to the ions for reducing this but 'irginia 22313-1450. DC k13-1450. | CFR 1.311. The informatic U.S.C. 122 and 37 CFR USPTO. Time will vary rden, should be sent to the ONOT SEND FEES OR | on is required to obtain a 1.14. This collection is a depending upon the in the Chief Information Of COMPLETED FORMS | or retain a benefit by estimated to take 12 dividual case. Any c ficer, U.S. Patent and TO THIS ADDRES | the pub minute ommen Trader S. SEN | lic which is to file (and s to complete, includin ts on the amount of tir nark Office, U.S. Dep D TO: Commissioner | by the USPTO to process) g gathering, preparing, and me you require to complete artment of Commerce, P.O. for Patents, P.O. Box 1450, |

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PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.



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| 10/552,110 | 07/03/2006 | Robert Peter Millar | 20747/300 | 4173 | |
| 75 | 90 12/04/2009 | EXAMINER | | | |
| Nixon Peabody | | | HA, JULIE | | |
| Clinton Square | | | ART UNIT | PAPER NUMBER | |
| P.O. Box 31051 Rochester, NY 14603-1051 | | | 1654 DATE MAII ED: 12/04/200 | 9 | |

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Application No. Applicant(s) 10/552,110 MILLAR, ROBERT PETER Notice of Allowability Examiner Art Unit JULIE HA 1654 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308. This communication is responsive to August 10, 2009. The allowed claim(s) is/are 1-11,15-33,35,37,39-41,43 and 45-60. 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). b) ☐ Some* c) ☐ None of the: a) 🛛 All 1. A Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)). * Certified copies not received: _____. Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. 4. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. CORRECTED DRAWINGS (as "replacement sheets") must be submitted. (a) Including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached 1) hereto or 2) to Paper No./Mail Date (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d). 6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL. Attachment(s) 1. Notice of References Cited (PTO-892) 5. Notice of Informal Patent Application 2. Notice of Draftperson's Patent Drawing Review (PTO-948) Interview Summary (PTO-413), Paper No./Mail Date 3. Information Disclosure Statements (PTO/SB/08), 7. Examiner's Amendment/Comment Paper No./Mail Date 4. T Examiner's Comment Regarding Requirement for Deposit 8. X Examiner's Statement of Reasons for Allowance of Biological Material Other . /Anish Gupta/ /Julie Ha/ Primary Examiner, Art Unit 1654 Examiner, Art Unit 1654

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REASONS FOR ALLOWANCE

1. The following is an examiner's statement of reasons for allowance: A compound comprising a gonadotrophin releasing hormone (GnRH) analogue conjugated to a steroid hormone is both novel and unobvious. The closest prior art is US Patent No. 6,211,224 (Chu et al). This patent teaches a method of administration of a GnRH antagonist and co-administration of an effective amount of an estrogen, a progesterone and an androgen (see claim 19). The prior art does not teach a GnRH analogue conjugated to a steroid hormone as described in the instant claims and application.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

2. Claims 1-11, 15-33, 35, 37, 39-41, 43, 45-60 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE HA whose telephone number is (571)272-5982. The examiner can normally be reached on Mon-Thurs, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anish Gupta/ Primary Examiner, Art Unit 1654 /Julie Ha/ Examiner, Art Unit 1654